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O THE UNITED STATES TRANSMITTAL LETTE DESIGNATED/ELECTED OFFICE (DO/EO/US) **CONCERNING A SUBMISSION UNDER 35 U.S.C. 371**

DOCKET NUMBER PC31759A/US

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

INTERNATIONAL FILING DATE INTERNATIONAL APPLICATION NO. 18 December 2002 (18.12.2002) 17 December 2003 (17.12.2003) PCT/US2003/040181 TITLE OF INVENTION Method of Using a Cox-2 Inhibitor and a Topoisomerase II Inhibitor as a Combination Therapy in the Treatment of Neoplasia APPLICANT(S) FOR DO/EO/US MASFERRER, Jaime L. Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. X The US has been elected (Article 31). 5. X A copy of the International Application as filed (35 U.S.C. 371(c)(2)) is attached hereto (required only if not communicated by the International Bureau). has been communicated by the International Bureau. is not required, as the application was filed in the United States Receiving Office (RO/US). An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). is attached hereto. has been previously submitted under 35 U.S.C. 154(d)(4). Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) are attached hereto (required only if not communicated by the International Bureau). have been communicated by the International Bureau. have not been made; however, the time limit for making such amendments has NOT expired. have not been made and will not be made. An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). 9. X An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). An English language translation of the annexes of the International Preliminary Examination Report under PCT 10. Article 36 (35 U.S.C. 371(c)(5)). Items 11 to 20 below concern document(s) or information included: An Information Disclosure Statement under 37 CFR 1.97 and 1.98. An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 12. X 13. X A preliminary amendment. An Application Data Sheet under 37 CFR 1.76. A substitute specification. A power of attorney and/or change of address letter. A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821-1.825. A second copy of the published International Application under 35 U.S.C. 154(d)(4). A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4). PCT Publ'n WO 2004/058302 A1; Internatioanal Search Report; International Preliminary Examination Report Other items or information: (w/replacement sheets); Return Receipt Poscard; Express Mail Label EV 726255863 US.

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mall Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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LLS APPLICATION NO. differown see 37 OFR (1.5) INTERNATIONAL APPLICATION NO.					ATTORNEY'S DOCKET NUMBER	
0.3. ATTEIONT	u.s. application no. if known see 37 FFR .5) PCT/US2003/040181			PC31759A/US		
The following fees have been submitted					CALCULATIONS	PTO USE ONLY
21. 🔀 Basic national fee\$300					\$ 300.00	
22. X Examination fee If International preliminary examination report prepared by USPTO and all claims satisfy provisions of					s 200.00	
PCT Article 33(1)-(4)\$100 All other situations\$200					200.00	
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23. X Search fee Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an						1
I I I I I I I I I I I I I I I I I I I					400.00	
International Search Report prepared and provided to the Office\$400 All other situations\$500					\$	1
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TOTAL OF 21, 22 and 23 = Additional fee for specification and drawings filed in paper over 100 sheets (excluding					700.00	
1 LDI coguence listing or computer program listing tiled in an electronic medium).						
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			up to a whole number)		750.00	į.
236 _{- 100} =	136 _{/50} =		3	x \$250	\$ 750.00	
Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest					\$ 0.00	
claimed priority	date (37 CFR 1.49		AN INTO EVEDA	RATE	\$	·
CLAIMS	NUME	BER FILED	NUMBER EXTRA		s	
Total claims	3	9 -20=		x \$ 50		
Independent cla	ims	2 -3=		x \$200	\$	
MULTIPLE DEPENDENT CLAIM(S) (if applicable) + \$360					\$ 0.00	
TOTAL OF ABOVE CALCULATIONS =					\$ 1,650.00	
Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.					0.00	
SUBTOTAL =					\$ 1,650.00)
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest					\$ 0.00	
claimed priority date (37 CFR 1.492(i)).					\$ 1,650.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied					\$	40.00
by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property TOTAL FEES ENCLOSED =					s	1,690.00
TOTAL FEES ENCLOSED =					Amount to be	T
					refunded:	\$
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					charged:	<u> </u>
a. X A check in the amount of \$ 1,690.00 to cover the above fees is enclosed.						
in the amount of \$ to cover the above fees.						
b. Please charge my Deposit Account No If the amount of a to constitute and a						
c. X The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit						
Account No. <u>08-0750</u> . A duplicate copy of this sneet is enclosed.						
d. Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not						
be included on this form. Provide credit card information and authorization on P10-2036.						
NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed						
and granted to restore the International Application to pending status.						
SEND ALL CORRESPONDENCE TO:						
Christian Smolizza (Reg. No. 46,319) SIGNATURE					<u></u>	
Pfizer Inc. Lydia N. Ne					enow	
150 East 42nd Street NAME					- <u></u>	
150/5/49S-IP Legal New York, NY 10017 52,530						
IISA REGISTRAT					TION NUMBER	



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:

Jaime L. Masferrer

Serial No:

TBA (§371 Application Based on PCT/US2003/040181)

Filed:

June 16, 2005

Title:

Method of Using a Cox-2 Inhibitor and a Topoisomerase II Inhibitor as a

Combination Therapy in the Treatment of Neoplasia

Group Art Unit:

TBA

Examiner:

TBA

Attorney Ref:

PC31759A/US

HDP Ref:

6794F-000032/NPN

June 17, 2005

TRANSMITTAL LETTER

Mail Stop PCT Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

Dear Sir/Madam:

The above-referenced patent application is a U.S. national phase application filed under 35 U.S.C. §371 based on International Patent Application No. PCT/US2003/040181 (filed December 17, 2003). Applicant respectfully submits the following:

- 1. Transmittal Letter to the United States Designated/Elected Office Concerning a Submission under 35 U.S.C. §371 (2 pages) (in duplicate).
- 2. Check for \$1,690.00 to cover the basic national fee, examination fee, search fee, extra sheets fee, and assignment recordation fee.
- 3. Executed Declaration and Power of Attorney (3 pages).
- 4. Assignment (2 pages).
- 5. Assignment Recordation Cover Sheet (1 page).
- 6. PCT Publication No. WO 2004/058302 A1 (239 pages).
- 7. International Search Report (3 pages).
- 8. International Preliminary Examination Report (with 4 replacement sheets) (8 pages).
- 9. Preliminary Amendment (9 pages).

U.S. Patent Application No. TBA (§371 Application Based of T/US2003/040181) Transmittal Letter June 17, 2005

10. Return Receipt Postcard.

Applicant has enclosed a check to cover the fees for this application (*i.e.*, basic national fee; examination fee; search fee; extra sheets fee; and assignment recordation fee). Applicant does not believe that any additional fees are due in connection with this filing. If, however, Applicant owes any additional fee(s) in connection with this filing, the Commissioner is hereby authorized to charge those fee(s) to Deposit Account No. **08-0750**.

Applicant requests that all correspondence for this application be sent to:

Christian Smolizza
Pfizer, Inc
150 East 42nd Street
150/5/49S-IP/Legal
New York, New York 10017
(212) 733-9094 (tel)
(212) 573-1939 (fax)

Applicant also requests that the Examiner call Christian Smolizza if any questions arise that can be addressed over the phone to expedite examination of this application.

Respectfully submitted,

Lydia N. Nenow, PTO Reg. No. 52,530

Harness, Dickey & Pierce, PLC 7700 Bonhomme, Suite 400

St. Louis, Missouri 63105

(314) 726-7500 (tel)

(314) 726-7501 (fax)

U.S. Patent Application No. (§371 Application Based on Γ/US2003/040181)
Transmittal Letter
June 17, 2005

CERTIFICATE OF MAILING UNDER 37 CFR § 1.8

I certify that this correspondence is being deposited with the U.S. Postal Service on June 17, 2005 with sufficient postage as first class mail (including Express Mail per MPEP §512), and addressed to Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Lydia N. Nenow, PTO Reg. No. 52,530

C. Neun

LNN/LVE